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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/805,813 02/26/97 MITSUHARA

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EXAMINER

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ART UNIT PAPER NUMBER

1649

ZD

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/805,813</b>	Applicant(s) <b>Ichiro Mitsuhashi, et al.</b>
	Examiner <b>Amy Nelson</b>	Group Art Unit <b>1649</b>

Responsive to communication(s) filed on Jun 21, 1999.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-20 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 14 remains objected to because of the following informalities:

At Claim 14, line 2, "Sarcotomin" is misspelled and should be changed to --Sarcotoxin--.

### ***Claim Rejections - 35 USC § 112***

2. Claims 1-3, 5-13, 15, 16, and 18-20 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record set forth in the last Official action mailed 12/16/98. Applicant's arguments filed 6/21/99 have been fully considered but they are not persuasive.

Applicant asserts that the present invention is not directed to a new class of nucleic acids, but rather to the use of a known class of nucleic acids in a novel way, *i.e.* methods for using the nucleic acids to confer desirable traits on plants (response, p. 3-4). Examiner responds that the instant claims are not directed to methods, but rather to fungal resistant transgenic plants and to expression cassettes therefore. Applicant has described only fungal resistant transgenic plants comprising an expression cassette comprising the sarcotoxin 1a gene. Applicant has not described

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other fungal resistant transgenic plants. Therefore, Examiner maintains that it is not clear from the instant specification that Applicant was in possession of the invention as broadly claimed.

3. Claims 1-3, 5-13, 15, 16, and 18-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to a recombinant gene, expression vector, and transgenic plant comprising the sarcotoxin 1a gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record set forth in the last Official action mailed 12/16/98. Applicant's arguments filed 6/21/99 have been fully considered but they are not persuasive.

Applicant asserts that one of skill in the art could practice the invention as broadly claimed by identifying a gene which encodes an anti-bacterial peptide, transform plants therewith, and screen the transformed plants to identify those with fungal resistance. Hence, Applicant asserts that only routine screening would be required to practice the claimed invention. Applicant further asserts that the cited post-filing date Epple publication provides evidence that other fungal resistant plants could be produced by transformation of plants with a gene encoding an anti-bacterial peptide, namely thionin (response, p. 4-6). Examiner responds that in the as-filed specification Applicant has provided no guidance for how to isolate other anti-bacterial genes or other anti-bacterial genes known in the prior art which could be used to produce the claimed transgenic plants with fungal resistance. Undue trial and error experimentation would be required

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to isolate other anti-bacterial genes given the lack of guidance in the instant specification. Furthermore, undue trial and error experimentation would be required to identify those anti-bacterial genes, from those isolated or from those taught in the prior art, which confer fungal resistance in transgenic plants. The novelty of the instant invention is the identification ~~of~~ by Applicant of an anti-bacterial gene which confers fungal resistance upon expression in transgenic plants. Applicant provides no guidance for other anti-bacterial genes which would similarly produce fungal resistant transgenic plants. The Epple reference does not help to obviate the rejection, because there is nothing in the instant specification which would direct one of skill in the art to a thionin gene rather than to any other anti-bacterial gene, as a gene which would confer fungal resistance to transgenic plants, hence the Epple reference is not directly supported by the teachings of the instant specification. The broad scope of the claims is not commensurate with the teachings of the specification, and therefore the rejection is maintained.

4. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 20, line 3, the term "and" is indefinite because it is not known how the peptide can be atacin, lysozyme, and cecropin. The term should be changed to --or--.

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***Claim Rejections - 35 USC § 102***

5. Claims 1-5, 10 and 20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Jaynes *et al.* (U.S. Patent 5,597, 945). This rejection is repeated for the reasons of record set forth in the last Official action mailed 12/16/98. Applicant's arguments filed 6/21/99 have been fully considered but they are not persuasive.

Applicant asserts that whereas Jaynes discloses anti-bacterial peptides, Jaynes does not teach their use in transgenic plants to confer fungal resistance. Applicant further asserts that Examples 11, 14 and 15 of Jaynes are prophetic, and are not supported by actual data (response, p. 6-7). Examiner responds that the transgenic plants of Jaynes are the same as the transgenic plants of the instant application, *i.e.* they are plants transformed with the Sarcotoxin 1a gene. Applicant fails to distinguish the plants of the instant application from the plants of Jaynes. Moreover, Jaynes has specifically taught the antifungal properties of the transgenic plants in the examples. It is not the position of the Examiner to question the validity of an issued patent.

Applicant argues that not all plants transformed with the anti-bacterial gene have fungal resistance. In fact, Applicant asserts that in an earlier Japanese application, Applicant showed that plants transformed with the Sarcotoxin 1a gene had bacterial resistance. Hence, Applicant asserts that the inherency argument is unfounded (response, p. 7). Examiner asserts, as discussed above, that the plants of Jaynes are the same as Applicant in that they are plants transformed with the Sarcotoxin 1a gene. Hence, all of the properties of the transgenic plants are an inherent property of the plants of Jaynes. While there may be a minor population of transgenic plants which do not

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properly express the gene or which have reduced anti-microbial activity, it is expected that the bulk of the population of the plants of Jaynes have both bacterial and fungal resistance. It is the burden of Applicant to structurally distinguish the plants of Applicant from those of Jaynes, and to provide side-by-side comparisons to demonstrate that the structurally distinct transgenic plants are functionally distinct as a result of the structural differences.

6. Claims 1, 2, and 20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Broekaert *et al.* (U.S. Patent 5,538,525). This rejection is repeated for the reasons of record set forth in the last Official action mailed 12/16/98. Applicant's arguments filed 6/21/99 have been fully considered but they are not persuasive.

Applicant asserts that the Broekaert patent does not inherently teach transgenic plants with fungal resistance, because not all transgenic plants have fungal resistance (response, p. 7). Examiner responds that, as discussed in the last Official action, Broekaert teaches transgenic plants with fungal resistance (Abstract, col. 4, for example), and hence all of the claim limitations have been previously disclosed by Broekaert.

***Claim Rejections - 35 USC § 103***

7. Claims 1-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jaynes *et al.* (U.S. Patent 5,597, 945) in view of Applicant's Admission. This rejection is repeated for the

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reasons of record set forth in the last Official action mailed 12/16/98. Applicant's arguments filed 6/21/99 have been fully considered but they are not persuasive.

8. Claims 1-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Broekaert *et al.* (U.S. Patent 5,538,525) in view of Applicant's Admission. This rejection is repeated for the reasons of record set forth in the last Official action mailed 12/16/98. Applicant's arguments filed 6/21/99 have been fully considered but they are not persuasive.

Applicant asserts that there was no motivation in the prior art to combine the cited references to obtain the claimed invention. In particular, Applicant asserts that whereas the hinge region for the tobacco chitinase gene was known at the time of the invention, as taught by Shinshi, there was no teaching of the use of said region in a recombinant expression vector and the advantages for recombinant protein production associated therewith. Lastly, Applicant asserts that no showing of unexpected results is required by Applicant, when the invention is nonobvious (response, p. 7-8). Examiner responds that the substitution of elements in an expression vector was well known to one of skill in the art at the time of Applicant's invention, and hence the claims of Applicant are considered routine variants of the teachings of the prior art. Different promoters and regulatory sequences are considered to be functional equivalents, and it would have been obvious to substitute one functional equivalent for another. Applicant has taught no particular purpose for the chitinase hinge region, and hence the inclusion of the hinge region in the vector is considered to be an insignificant, matter of choice, and not a nonobvious modification of the prior

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art references. Although Shinshi has not taught the advantages of the inclusion of the hinge region in an expression vector, neither has Applicant.

See In re Kuhle 188 USPQ 7 (CCPA 1975), which teaches that the use of a claimed embodiment which solves no apparent problem and provides no unexpected result is deemed an obvious matter of choice.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Amy J. Nelson, Ph.D.

July 20, 1999

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
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